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6713-Dr. Wi-ka

REMARKS

Provisional Obviousness-type Double Patenting Rejections

The applicants maintain their position from the previous response. However, they would like to inform the examiner that SN: 09/963,161 (listed as 09/693,161 in the office action) and 09/428,421 have been abandoned. (Also, it is believed that the examiner intends to mean SN: 09/328,727 rather than 09/328,792). If any of this information is in error, please contact the undersigned.

35 U.S.C. 112, second paragraph rejection

Claims 1 and 6 remain rejected for the reasons which are addressed below:

- (i) "lipids and lipophilic constituents"
- (ii) "derivative" - the entire phrase is --cationic cellulose derivatives--
- (iii) "condensation products of polyglycols and amines"

The applicants' response from the previous office actions are to be considered repeated here as the previous response provided the criteria and evidence that the terms in question had defined meaning in the art and the examiner's rejection provided no countervailing evidence to support her position.

Comment on Examiner's Response to Arguments

The examiner's reliance on *In re Young* (for "lipids...lipophilic constituents" and "derivative") is not believed to be well founded for two reasons. First, the reference to previous patents was not only to show that these terms had been allowed in the past but also to provide evidence that these terms had acquired meaning in the art and that one of ordinary skill in the art would be apprised of these meanings. Examiner has never provided her own evidence as to why one of ordinary skill in the art would find these terms to be vague and indefinite.

Second, while the examiner is not precluded from using case law to support her positions, it is unclear what portion and how the fact pattern of *In re Young* is similar to that found in this application, especially since the examiner is relying on case law which pre-dates the 1952 Patent Act. The examiner is reminded that MPEP 2144 states that "Legal Precedent Can Provide the Rationale Supporting Obviousness Only If the Facts in the Case Are Sufficiently Similar to Those in the Application"

With regard to the "lipids...and lipophilic constituents" portion of the rejection, it appears that the examiner objects to the fact that lipids could be considered lipophilic constituents. However, there is no

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requirement that there cannot be an overlap ("double inclusion) among listed elements (see e.g. MPEP 2173.05(h) - Alternative Limitations).

With regard to "derivative", the applicants' once again repeat that the claims must be considered "as a whole" and that the entire phrase in question is "cationic cellulose derivatives". The examiner appears to be under the impression that the term "derivative" is automatically indefinite. This is simply untrue. Again, no evidence has not been provided as to why these terms which have definite meaning within the art would not be understood by one of ordinary skill in the art. Put another way, if a compound were placed before one of ordinary skill in the art, would that artisan be able to determine if the compound possessed each of the elements of the phrase? The applicants believe this is unquestionably "yes" as cellulose is a well known compound, cationic is well known concept in the chemical arts and one of ordinary skill in the art would be able to determine between cellulose and a cellulose derivative.

With regard to "condensation products of polyglycols and amines" it is unclear what the examiner does not understand about the phrase as the questions raised are not germane to what the phrase defines, i.e. a product formed by reacting a polyglycol with an amine (i.e. a condensation reaction). Again, placing a compound before one of ordinary skill in the art, would that skilled artisan be able to determine if each of the elements were met? The answer is "yes".

To date the examiner has never offered her own suggestion(s) as to what would be appropriate claim language. It is presumed that the examiner is aware of the effects of *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.* series of decisions on patent prosecution, i.e. any amendment related to patentability can be viewed as prosecution history estoppel. In this environment, applicants representative cannot in good faith modify the claims on behalf of their clients based on the examiner unsupported reasons of record especially when specific evidence has been provided by the applicants. Even if the applicants were amenable to modifying the claim, they cannot afford to guess at what the examiner would find to be permissible terminology. With this in mind, section 2173.02 of the MPEP is reproduced below:

The examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph is whether the claim meets the threshold requirements of clarity and precision, *not whether more suitable language or modes of expression are available*. When the examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. *Examiners are encouraged to suggest claim language to applicants to improve clarity or precision of the language used, but should not reject claims or insist on their own preferences if other modes of expression selected by applicants satisfy the statutory requirement.* (see MPEP 2173.02)

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35 U.S.C. 103(a) rejection

- (1) Claims 1, 3-6, 7, 8 and 11-12 were rejected by the examiner as being obvious over Fänger et al. (U.S. Patent 6,153,204) *in view of Albacrys*???

The examiner acknowledges two differences between the applicants' claimed invention and the Fänger et al. reference, i.e. the claimed viscosity parameters and the inclusion of cationic polymers. The examiner relies on the Albacrys reference to account for these differences which the applicants believe is an improper combination.

Establishing a *prima facie* case of obviousness requires an "as a whole" consideration of the applicants' claimed invention and that of the prior art. Combination of the references also requires a motivation for making the appropriate combination or modifications to the primary reference. This motivation must come without the benefit of hindsight reconstruction using the applicants' claims as a template. This point is exemplified by the holding in *In re Fine*:

"Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it 'cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And 'teachings of references can be combined *only* if there is some suggestion or incentive to do so.' *Id.* Here the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination...

It is essential that 'the decisionmaker forget what he or she has been taught at trial about the claimed invention **and cast the mind back to the time the invention was made**...to occupy the mind of one skilled in the art **who is presented only with the references**, and who is normally guided by the then-accepted wisdom in the art.' *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

see *In re Fine*, 5 USPQ2d 1596, 1599, 1600 (Fed. Cir. 1988).

Applying this standard to the present application, the question becomes what would one of ordinary skill in the art have deemed to have been obvious as of 23 May 2000 (the filing date of this application) having the Fänger et al. and Albacrys references before him **but without the present claims before them**.

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The key elements of Albacarys' invention (a water soluble substrate; at least one lathering surfactant impregnated onto the substrate and a skin care component) bears no relation to the key elements of Fänger et al.'s invention (use of n-octenylsuccinate esterified starch - an anionic compound) and appears to be relied upon for its compendium of additional ingredients. However, the very breadth of the Albacary's reference also serves to weaken its effectiveness as a secondary reference as there is virtually an infinite number of additional ingredients which can be selected. From this teaching, the examiner asserts that it would have been obvious to select cationic polymers from Albacary's and add it to the teachings of Fänger et al. This is precisely the type of "picking and choosing" which is precluded when combining references.

Moreover, when considering the teachings of Fänger et al. as a whole, it is clear that the n-octenylsuccinate esterified starch (an anionic compound) is the key element of the invention. As such, even if it was permitted to "pick and choose" elements, it is unclear why one of ordinary skill in the art would be compelled to add a cationic compound to a compositions where the signature ingredient is anionic.

With regard to viscosity limitation, there is a further teaching away from inherency as even if the cationic polymer element were permitted to be combined, the modified teachings of the Fänger et al. invention would include an additional element, i.e. the n-octenylsuccinate esterified starch, which are not express elements of the applicants' claimed invention. Therefore, the examiner still has the additional burden of showing that the applicants invention with the presence of n-octenylsuccinate esterified starch has the viscosity of the applicants claims. *Prima obviousness* is a legal conclusion based on fact. However, no facts have been presented which supports

- (2) Claims 2, 9 and 10 were rejected by the examiner as being obvious over Fänger et al., *id.*, in view of Albacarys et al. (U.S. Patent 6,338,855) further in view of Mahieu et al. (U.S. Patent 5,616,746) and Phillippe et al. (U.S. Publication 2002/0064539).

It is believed that if the Fänger et al. in view of Albacarys et al. rejection should fall, these rejections would also fall. However, for completeness' sake it is presented that when considering the use of Mahieu et al. and Phillippe et al. one must also consider what would have been obvious as of 23 May 2000 without having the applicants' claims before them.

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Fänger et al., Mahieu et al. and Phillippe et al. are each directed toward compositions wherein the centerpiece of their respective inventions are different compounds (n-octenylsuccinate esterified starch; derivatives of amino deoxyalditols; spider silk proteins, respectively) which bear no relationship to the other (Albacarys is directed toward a substrate). As such, there is no assurance that the appropriate substitutions could be made much less assurances that there is guidance that would've made such a modification obvious to the skilled artisan on 23 May 2000 without the present claims before them.

Comment on Examiner's Response to Arguments

The examiner stated that the applicants' arguments against the inherency of the viscosity limitations is not persuasive. However, there is no viable explanation as to why the examiner elected to adopt this position. The two case law citations offered by the examiner, i.e. *In re Aller* and *In re Boesch* do not speak to the issue of inherency and are not even relevant to the issue of "optimization of ranges" unless a results effective parameter has been identified by the prior art; said parameter was not identified (see MPEP 2144.05 section II which is the very next section after the *In re Aller* citation which states that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)."

In addition, the examiner appears to be making a holding of obviousness based strictly on the case law. While this is not automatically improper, it is the examiner's burden to show that the fact pattern of the case law so closely adheres to the facts of the present application that one is compelled to follow the decision of the case law. "No per se rules of obviousness have been established by precedent, and reliance on any such rules that eliminate the need for fact-specific analysis of claims and prior art is legally incorrect and must cease, since use of per se rules in obviousness determination is inconsistent with 35 U.S.C. § 103, which entitles applicant to issuance of otherwise proper patent unless Patent and Trademark Office establishes that invention, as claimed in application, is obvious over cited prior art, based on specific comparison of that prior art with claim limitations." see *In re Ochiai*, 37 U.S.P.Q. 1128, (Fed. Cir. 1995) and also MPEP 2144.

As stated in the earlier response, the question of obviousness is a legal conclusion based in fact; while the examiner is the primary finder and trier of these fact, there has never been a factual determination for why the examiner believes the viscosity limitation is an inherent property of the prior art.

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Closing

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.116 (7 pages total) is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

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